UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO: **ALL PLAINTIFFS LISTED IN EXHIBIT A TO PLAINTIFFS' MOTION**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

ETHICON'S MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE CERTAIN OPINIONS AND TESTIMONY OF CYNTHIA BERGMANN, M.D.

INTRODUCTION

Despite Dr. Bergmann's professional education, training, her years of experience and her review of medical literature, *see generally*, Cynthia Bergmann Report Regarding the Ethicon TVT Incontinence Sling ("Report"), Feb. 29, 2016, attached to Plaintiffs' Motion to Exclude [Doc. 2046] as exhibit C and Reliance List, exhibit D to Plaintiffs' Motion to Exclude, Plaintiffs seek to preclude Dr. Bergmann from testifying about "Ethicon documents," alternative products and procedures, Ethicon's training programs, particle loss, degradation, and the adequacy of the TVT IFU. They also seek exclusion of Table 1 to Dr. Bergmann's Report. None of Plaintiffs' arguments has merit, however, as Dr. Bergmann's opinions comply with the standards of *Daubert* and Fed. R. Evid. 702, and Plaintiffs' Motion should be denied.

FACTUAL BACKGROUND

Plaintiffs do not challenge Dr. Bergmann's qualifications or her expertise as a pelvic surgeon. Plaintiffs' Memorandum in Support of Motion to Exclude Certain Opinions and

Testimony of Dr. Cynthia Bergmann [Doc. 2048] ("Plaintiffs' Mem.") at 1. This is because Dr. Bergmann is unquestionably qualified to render her opinions here. She has been board certified in obstetrics and gynecology since 1986 and is a fellow of the American College of Obstertricians and Gynecologists. Report at 1-2. Since around 2001, polypropylene slings have been her surgical treatment of choice to treat SUI, although she also offers non-surgical choices like lifestyle changes, pelvic floor stimulators and pessaries. *Id*.

She has used the TVT sling in hundreds of surgical procedures. Cynthia Bergmann Report Regarding the Ethicon TVT Incontinence Sling (Report"), Feb. 29, 2016, at 16, attached to Plaintiffs' Motion to Exclude [Doc. 2046] as exhibit C; Cynthia Bergmann, M.D. (3/15/16) Dep. at 24, attached to Plaintiffs' Motion to Exclude as exhibit E. Despite her extensive surgical experience implanting TVT, it is clear from her general report that her opinions in this litigation are also based on her extensive review of medical literature, including Level 1 evidence such as Cochrane Review meta-analyses assessing thousands of patients, and numerous randomized controlled trials, not to mention public statements by medical societies in the fields of urology, gynecology, and urogynecology. Bergmann Report at 9-17.

ARGUMENT

While this Court is charged with the role of gatekeeper under *Daubert* and its progeny, courts must also recognize that Rule 702 "was intended to liberalize the introduction of relevant expert evidence." *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999). Expert testimony that is more likely "to mislead than to enlighten" should be excluded, but proper expert testimony with which the adverse party simply disagrees is best tested by "vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof." *Id.*

I. Dr. Bergmann Can Address Ethicon Documents.

Plaintiffs argue that Dr. Bergmann should be precluded from testifying about Ethicon documents that she did not review. Plaintiffs' Mem. at 3-4. This challenge arises as a result of a series of questions put to Dr. Bergmann by Plaintiffs' counsel in her deposition, which resulted in Dr. Bergmann's candid admission that she had not reviewed all of the internal Ethicon documents. *See* Bergmann Dep. at 87; 94.

Yet Dr. Bergmann has not been designated to opine on these internal Ethicon documents, which explains why she had not reviewed every page of every document before being questioned about them by Plaintiffs' counsel. Notwithstanding this, to the extent that Plaintiffs seek to use such documents in an attempt to discredit Dr. Bergmann's opinions, she is permitted to review and comment on these documents. Plaintiffs cannot examine her on these documents and then object to her response.

Additionally, Plaintiffs' motion is overly broad in that it seeks to preclude Dr. Bergmann "from testifying about any Ethicon documents or their contents…." Plaintiffs' Mem. at 4. Yet Dr. Bergmann reviewed the TVT IFU and Ethicon patient brochures and offered opinions on these documents in her Report. *See* Report at 18-20. Dr. Bergmann is certainly entitled to opine on these documents, and any other documents noted on her Reliance List that she reviewed. Plaintiffs' Motion should be denied as overly broad, and any objection to a particular document is best handled at trial.

II. Dr. Bergmann is Qualified to Offer Opinions About Alternative Devices and Procedures.

A. Dr. Bergmann is qualified by experience to discuss risks and complications of other treatments for SUI.

Plaintiffs miss the mark in their argument that Dr. Bergmann is precluded from testifying about risks and complications associated with the pubovaginal sling because she has not personally implanted the device. Plaintiffs' Mem. at 4. An informed surgeon such as Dr. Bergmann knows about the morbidity and complications of the different surgical options that are available to treat a particular medical condition in order to determine the best choice for her patients. Included in this evaluation is how such procedures compare to one another and information from studies and medical literature related to them. The evaluation would also focus on the surgical procedure itself in terms of how it is performed and any risks related to the surgical technique. Therefore, Dr. Bergmann's overall education and training, along with her review and evaluation of medical literature and studies as to other procedures, renders these opinions appropriate.

Dr. Bergmann discusses a host of options to treat SUI, both surgical and non-surgical. *See* Report at 5-8. The fact that Dr. Bergmann has chosen not to perform a particular surgical option does not disqualify her from offering opinions about it as an alternative method, including how the procedure is generally performed, what recovery time can be expected, the complication rates associated with the procedure, and the efficacy of the procedure. She is qualified to discuss such matters based both on her familiarity with it from her partner and colleagues and her review of literature on the subject. In fact, her decision not to pursue a particular option rests on her education and experience as well as considerations of morbidity and complications of that procedure.

In addition, Dr. Bergmann's decision to use TVT is informed by her analysis of the risks and complications of other available procedures and products. She contrasts the morbidity of pubovaginal sling procedures with that of the TVT – "Midurethral sling procedures are

minimally invasive, and much less morbid than traditional anti-incontinence procedures such as the Burch procedure or pubovaginal slings." Report at 7. She also discussed the published medical literature regarding complication rates associated with pubovaginal sling procedures. Report at 10-11. She is informed by professional organization position statements on pubovaginal slings and midurethral slings. Report at 15 (discussing ACOG & AUGS Nov. 2015 practice bulletin). All of this is well-within her expertise fashioned over 30 years of practice and from her education. Plaintiffs' Motion should be denied.

B. Dr. Bergmann is qualified to discuss other claimed mesh alternatives.

Plaintiffs attack what was a mere generalization by Dr. Bergmann related to her use of the term "Gynemesh" to refer to polypropylene mesh to argue that she is not qualified to rebut other mesh alternatives suggested by Plaintiffs' experts. Plaintiffs' Mem. at 5. In fact, both quotes included in the Plaintiffs' Memorandum are consistent with that generalization. *See* Plaintiffs' Mem. at 5. When asked if TVT is made of Gynemesh she said "yeah, it's the same material." *Id*. In a general sense, this is correct—both TVT and Gynemesh are made of Prolene polypropylene. Similarly, when asked if the TVT mesh is different than Gynemesh PS, she said "yeah, because there's several different grades of Gynemesh…." *Id*. Given that Gynemesh PS is used to treat pelvic organ prolapse and not SUI, her explanation of different grades is easily interpreted as different products made of Prolene mesh depending on the indication.

Plaintiffs distort Dr. Bergmann's testimony and her Report by arguing that "her testimony contradicts her own report which states that Gynemesh is an *alternative* material to Prolene (the material of which the TVT device is actually made.)" Plaintiffs' Mem. at 5 (emphasis in original). To the contrary, her Report addresses the position of *Plaintiffs' experts* that *Gynemesh PS* is a claimed alternative to TVT. Report at 16. She then correctly notes that

Gynemesh PS has not been the subject of peer-reviewed literature for use as a SUI sling. *Id*. Thus, Plaintiffs' characterization of her lack of knowledge about the mesh in TVT is incorrect and fundamentally flawed.

Nor does Dr. Bergmann's reference in her deposition to "Gynemesh" render her unqualified to offer opinions about the type of mesh used in the TVT or feasible alternatives to that mesh. Her Report readily establishes that she knows that TVT is made of Prolene. Report at 9. Her experience implanting hundreds of TVT slings, Bergmann (3/15/16) Dep. at 54:24 – 55:1, and the positive results she has seen in her patients with those slings support her assertion that it is better than the alternatives proffered by Plaintiffs' experts. This is also bolstered by the few complications she has seen in her surgical practice related to TVT. *Id*. at 50:16 – 51:10; Report at 9-10. Finally, her knowledge of the literature and studies reflecting that Plaintiffs' identified alternatives are not SUI sling products renders her opinions appropriate here. Report at 16.

C. Dr. Bergmann has sufficient personal experience to opine on Ethicon's training programs.

Plaintiffs claim that Dr. Bergmann's attendance at only two Ethicon training sessions precludes her offering opinions about that training. Plaintiffs' Mem. at 6. Dr. Bergmann, however, thoroughly described the Ethicon training she attended at her deposition. Bergmann (3/15/16) Dep. at 35:10-21; 36:19-40:9. Plaintiffs seem to fault her for not attending more than the requisite training sessions required in order for her to become comfortable using the device in her practice. Plaintiffs' Mem. at 6. That simply is not logical given that Dr. Bergmann began using the device in her practice to great success following her training, so there was no need for her to undergo additional training.

Dr. Bergmann's opinions are based on direct personal experience attending Ethicon's training programs, which is the best qualification for this type of opinion. She explained that the training involved classroom instruction, instruction on SUI, data involving the safety and efficacy of the TVT, and a presentation on how TVT is implanted. Bergmann (3/15/16) Dep. at 35. Next, those attending training did "passes with models first" and then performed the surgery in a cadaver lab. *Id*. She provided a step by step explanation of how she was trained to implant the TVT. Bergmann (3/15/16) Dep. at 36-39. She testified that once this portion of the training was complete, trainees observed the procedure on four or five patients. Bergmann (3/15/16) Dep. at 40. All of this establishes that she most certainly knows what the training entails because she went through the training herself.

Plaintiffs claim that she is not qualified to discuss Ethicon training because she has not taught other physicians on the use of the device. Plaintiffs' Mem. at 6. She was, in fact, designated as a trainer for TVT in 2008 because Ethicon representatives "liked the way that I did the procedure," and Ethicon sent several of their representatives "in training" to watch her surgeries. Bergmann (3/15/16) Dep. at 14. The fact that she conducted no official training for physicians does not under cut her familiarity with Ethicon's training.

Plaintiffs' fault Dr. Bergmann because she no longer has the training documents provided to her in 2003. Plaintiffs' Mem. at 6. Plaintiffs cite no law to support this assertion. Failure to maintain training material for 13 years does not disqualify her opinions here, and she was under no obligation to keep them. Everything that counsel opposite takes issue with is properly the subject of cross-examination rather than a basis for excluding her opinions. *See Daubert v. Merrell Dow Pharm., Inc*., 509 U.S. 579, 596 (1993) ("Vigorous cross-examination, presentation

of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means" of attacking evidence).

III. Dr. Bergmann's Personal Clinical Experience is Sufficient for her Opinions Related to Particle Loss.

Plaintiffs claim that because Dr. Bergmann has seen no clinically significant particle loss in her hundreds of TVT implantations, yet isolated Ethicon documents indicate that particle loss may have sometimes occurred, then Dr. Bergmann is foreclosed from testifying to her personal surgical experience because of this alleged "conflict." Plaintiffs' Mem. at 7. Plaintiffs fail to cite to any evidentiary standard that makes this a requirement for her opinions to be admissible. To the extent that Plaintiffs believe this is inconsistent, then such inconsistencies are ripe for cross-examination.

Even if this were somehow a requirement, the documents cited by Plaintiffs in their Memorandum are not about particle loss in the clinical context. *See* Plaintiffs' Mem. at 7. Plaintiffs assert that Dr. Bergmann cannot comment on the particle loss noted in the Ethicon documents because she does not "know what Defendant's definition of particle loss was" as discussed in the documents presented to her at her deposition. Plaintiffs' Mem. at 7. Dr. Bergmann explained that it was not possible to tell from the limited universe of information presented to her at her deposition if the particle loss discussed in the documents was "particles in the kit . . . [or] particles found in the patient." Bergmann (3/15/16) Dep. at 98. This difference may theoretically matter clinically, but it does not change the fact that Dr. Bergmann has not seen particle loss in her clinical practice. *Id*. at 98. It is also not a requirement for admissibility that her definition of particle loss be the same as Plaintiffs' counsel's definition or even Ethicon's internal definition. Dr. Bergmann can opine in terms of clinical impact in her

experience. Plaintiffs' motion again addresses matters that are areas for cross-examination rather than exclusion.

IV. Dr. Bergmann's Opinions About Degradation are Reliable.

Plaintiffs mischaracterize the basis for Dr. Bergmann's opinion that there is no clinically significant degradation of TVT, wrongly contending that her opinion is "only" based on her "common sense." Plaintiffs' Mem. at 8. Plaintiffs select a single question and response out of 7 pages of deposition testimony about degradation to attempt to undercut Dr. Bergmann's opinion here. This misstatement is misleading and unfair.

Dr. Bergmann acknowledges that degradation can occur because "we know that anything we implant in the body will degrade over time." Bergmann (3/15/16) Dep. at 89. That said, she cannot identify any clinically meaningful degradation of TVT based on her personal experience with hundreds of patients or based on the medical literature related to polypropylene.

> Q. And you stated in your report that you don't believe there are -- let me find the exact one. It's on Page 17 as well. And it's that first paragraph right where we stopped reading last time.
> You state: "As far as degradation is concerned, again, I have not seen clinically significant degradation of the TVT mesh in my practice, nor have I seen clinically significant degradation described in the published literature, even in those patients on whom I re-operated following a prior mid-urethral sling procedure." What do you mean by "clinically significant degradation"?
>
> A. I think the longest implanted mesh that I have taken out had been in for seven years and it was still very strong.
>
> Q. How do you know it was very strong?
>
> A. Because in taking it out you have to grasp it, you put tension on it to be able to dissect off the surrounding tissues. And if it were fragile, if you put any tension on it, it would crumble and it does not.
>
> Q. So clinically –

A. It's much stronger than the surrounding tissues are.

Q. So clinically significant degradation to you means that the device actually crumbles?

A. Well, clinically significant would mean it would have to be falling apart and it doesn't.

Bergmann (3/15/16) Dep. at 89-90.

In addition, Dr. Bergmann testified that she knew of no randomized controlled trials that show that the TVT mesh degrades in a clinically significant way. *Id*. at 120:13-16. "A fundamental principle of evidence-based medicine . . . is that the strength of medical evidence supporting a therapy or strategy is hierarchical. When ordered from strongest to weakest, systematic review of randomized trials (meta-analysis) is at the top, followed by single randomized trials, systematic reviews of observational studies, single observational studies, physiological studies, and unsystematic clinical observations." *See* Federal Judicial Center, Reference Manual on Scientific Evidence 723-24 (3d ed. 2011). Dr. Bergmann cites numerous Cochrane reviews, systematic reviews, and meta-analyses throughout her report. *See, e.g.*, citations to studies by Ford, Schimpf, Novara, Tommaselli studies, Report at 7-8; 11-17.

In addition to the medical literature, Dr. Bergmann cites to the "Frequently Asked Questions by Providers" jointly issued by the American Urogynecological Society (AUGS) and Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstructions's (SUFU), two prominent medical societies in this field. Bergmann Report at 17. In that publicly-issued statement, AUGS/SUFU specifically conclude that the allegation of degradation is not supported by the extensive peer reviewed literature on polypropylene, which has followed patients out to seventeen years. AUGS/SUFU March 2014 FAQ to Providers, Ex. A. In support of its statement, AUGS and SUFU cite the 17-year follow up study by Nilsson et al. on the Gynecare

TVT that degradation, if it exists, has no clinical impact upon patients. As such, Dr. Bergmann's opinions related to degradation are grounded on the empirical results of scientific studies and her experience as a surgeon – not simply her "common sense."

V. Dr. Bergmann Can Testify to the General Knowledge of Pelvic Surgeons and its Impact on the Necessary Contents of the TVT IFU.

Dr. Bergmann is not designated as an FDA/regulatory expert; nor has she been offered to testify about what Ethicon knew or did not know. In her Report, she challenges *specific* criticisms by Plaintiffs' experts that the IFU is inadequate for failing to "warn of pain or dyspareunia." Report at 19. She notes that pelvic surgeons know such surgery includes the risks of pain, dyspareunia, recurrence of incontinence, re-operation, infection, wound healing complications, etc. And surgeons know that those adverse events or any others could be temporary or they could be permanent." *Id*. She discusses the FDA Public Health Notification that addressed possible complications from mesh used for vaginal repair, including "erosion through the vaginal epithelium, infection, pain, urinary problems, and recurrence of prolapse and/or incontinence." *Id*. The Notification "also indicated that '[t]here were also reports of bowel, bladder, and blood vessel perforation during insertion. In some cases, vaginal scarring and mesh erosion led to a significant decrease in patient quality of life due to discomfort and pain, including dyspareunia.'" *Id*. Thus, rather than saying that risks she has never seen did not need to be in the IFU, she testified to a host of risks and complications that would be appreciated by pelvic surgeons as risk of any pelvic surgery, and some as specifically identified to surgery using mesh. Such risks, therefore, would not have to be included in the IFU. *Id*.

Plaintiffs' argument on this issue is that Dr. Bergmann does not know FDA regulations as they pertain to labeling of medical devices. Plaintiffs' Mem. at 10. This argument rests on

the supposition that expertise in FDA regulations related to requirements for IFUs is mandatory for these opinions.

Yet, the job of an expert witness is to provide the facts to which the court can apply the law. It is not the expert's job to provide the court with the law. This Court, in fact, has excluded testimony which not only stated facts but also expressed a legal conclusion. *In re Ethicon, Inc. Pelvic Repair Systems Product Liability Litigation (Lewis)*, 2014 WL 186872, *20 (S.D. W. Va. 2014), *citing United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006). The important question here is whether Dr. Bergmann's testimony was consistent with the law to be applied to the case, and not whether she herself could articulate the governing legal standard. If she had attempted to do that, her testimony would have been excluded.

This Court's prior decisions with regard to defense experts' testimony on product warnings have concerned testimony from an expert that, because she had not experienced certain risks in her clinical practice, then her opinion that such risks need not be contained in the IFU was improper. *Bellew v. Ethicon, Inc.*, No. 2:13-cv-22473, Memorandum Opinion and Order (*Daubert* Motions), Doc. 265 at 35 (S.D. W. Va. Nov. 20, 2014). That is not what Dr. Bergmann does here. Nor does she testify that, based upon the risks and complications she has seen in her clinical practice, "there are no other possible risks or complications that should have been included." *Mathison v. Boston Scientific*, 2015 WL 2124991, *27 (S.D. W. Va. May 6, 2015). Instead, her warning opinion and opinion that the IFUs are adequate is tied to the knowledge of pelvic floor surgeons based on their education and experience from performing pelvic surgery and keeping abreast of health notifications and medical developments. Thus, the circumstances here are different from those in *Bellew* and *Mathison*, and Dr. Bergmann's opinions here are proper.

The legal principle that controls here is that a device manufacturer's duty to warn of adverse events is limited to events unique to the device. It does not include a duty to warn of risks commonly known to the surgeons who use the device. As stated generally in the RESTATEMENT (THIRD) OF TORTS: PRODUCT LIABILITY §2, cmt. j, a product seller "is not subject to liability for failing to warn or instruct regarding risks and risk-avoidance measures that should be obvious to, or generally known by, foreseeable product users." See also RESTATEMENT (SECOND) OF THE LAW OF TORTS §§388(b), 402A, cmt. j; *Roney v. Gencorp*, 654 F. Supp. 2d 501 (S.D. W. Va. 2009)(adopting "sophisticated user" defense in §388).

This limitation on the duty to warn is recognized in medical cases as well. There is no duty to warn of risks that implanting surgeons commonly know. *See Brooks v. Medtronic, Inc*., 750 F.2d 1227, 1230 (4th Cir. 1984) (duty to warn only of dangers "not well known to the medical community"). In fact, the FDA regulations recognize that that information may be omitted from labeling "if, but only if, the article is a device for which directions, hazards, warnings and other information are *commonly known* to practitioners licensed by law to use the device." 21 C.F.R. §801.109(c)(emphasis added).

The TVT IFU restricts the class of surgeons who are to use the device. It contemplates that users will be familiar with traditional surgical techniques used to treat stress urinary incontinence. *See* TVT IFU at 28 ("Users should be familiar with surgical techniques for bladder neck suspensions and should be adequately trained in implanting the TVT system before employing the TVT device."), Ex. B.

So the important question with respect to Plaintiffs' failure to warn claim is what "hazards" are "commonly known" to surgeons familiar with pelvic surgery, including surgery to address SUI. Ethicon had no duty to warn of adverse events "commonly known" to those

surgeons. Its duty was to warn of adverse events that were unique to the mesh devices. If Plaintiffs intend to argue at trial that Ethicon's IFU failed to disclose certain risks, Ethicon is fully entitled to defend such claims by demonstrating that those risks were obvious to the users of the product (pelvic surgeons), and therefore, did not need to be disclosed.

This Court has permitted experts to opine about risks they perceive from surgery using mesh and whether those risks are covered by the applicable IFU. *See Huskey,* 29 F. Supp. 3d 691, 703, 719 (S.D. W. Va. 2014) (Drs. Rosenzweig and Blaivas adequately experienced physicians qualified to testify to risks of surgery and whether the risks were addressed in the IFU despite lack of expertise in FDA regulations or standards governing device warnings); *Trevino v. Boston Scientific Corp.*, 2:13-cv-01617, 2016 WL 1718836, at *13-14 (S.D. W. Va. April 28, 2016) (Dr. Shull permitted to testify on adequacy of product instructions for use "from a clinician's perspective"). Here, Dr. Bergmann relies upon her extensive experience as a clinician to underpin her opinions as expressly permitted by Rule 702. She offers opinions about the IFU not simply from her perspective as an experienced, knowledgeable, skilled, educated, and trained pelvic surgeon who implants these devices regularly, but as an experienced, knowledgeable, skilled, educated, and trained pelvic surgeon who performs many other types of pelvic surgeries. Dr. Bergmann is precisely the type of experienced, qualified witness that a jury should be permitted to hear based on the criteria in Rule 702.

Plaintiffs contend that Dr. Bergmann should be excluded from discussing the IFU because she was "dumbfounded" that risks such as dyspareunia and chronic pain were added to the 2015 TVT IFU, and she "does not know why..." Plaintiffs' Mem. at 9-10. Dr. Bergmann acknowledges that she has not seen certain of the enumerated risks in the 2015 TVT IFU during her career as a pelvic surgeon. Bergmann (3/15/16) Dep. at 67. When asked if she knew "why"

Ethicon would put those risks in the updated TVT IFU, she admitted she did not know. *Id*. at 66. Dr. Bergmann's opinion that risks of pelvic surgeries known to trained surgeons need not be included in the IFU is unrelated to Ethicon's decision to update the IFU in 2015. The fact that Dr. Bergmann did not know why Ethicon chose to add to the IFU adverse reactions that surgeons already know does not render her testimony unreliable or inadmissible.

Dr. Bergmann has used the TVT device approximately 250 times. She knows how to implant it. She knows the complications that can result from use of mesh slings based both in her extensive personal experience and her review of the pertinent medical literature and Level 1 evidence. She did not say that certain risks should not have been in the IFU because she has not personally experienced them. Rather, she offered opinions about the adequacy of the IFU in terms of risks associated with pelvic floor surgery that are generally known to pelvic surgeons. And this she is unequivocally qualified to do.

VI. Dr. Bergmann's Table Attached to her Report is a Proper Summary of Some of the Information Upon Which She Relied.

Dr. Bergmann prepared a summary of some of the information from the medical literature in Table 1 of her Report. As she explained, the table "is not a head-to-head comparison, but a compilation of information about different methods." Report at 22. It was intended as a useful compilation of information derived from studies upon which she relied in support of her opinions:

> Well, because I considered this instructional to try to compare -- since there are no head-to-head, randomized, controlled trials comparing all of these different methods, and I thought that this would be a simpler way to look at each individual procedure and looking at various aspects of it, how hard it is to do, what the impact is on the patient, risk of retention, et cetera.

> So it was just -- it was a compilation of things similar to what the Cochrane report does when they compile various studies.
>
> . . .
>
> And I just found it a very simple way to refer to the different types of things rather than write it out as a paragraph or two or five.

Bergmann (3/15/16) Dep. at 106: 8-18; 107: 5-7. It constitutes a "way of looking at them to make the data more accessible." *Id*. at 107:22-23.

Plaintiffs fault her for failing to "perform an exhaustive search for medical literature or create exclusion or inclusion material" in creating the table. Plaintiffs' Mem. at 11. They likewise assert that there is not "legend or key" for her rating system. *Id*. at 10. Dr. Bergmann, however, explained her rating system, which is based on her opinions about the procedures from her own experience:

> Q. And can you tell me for the skill level required what that key means of the pluses?
>
> A. Oh, it's from difficult -- like two pluses would be fairly simple, three pluses moderately difficult, and four pluses more difficult.
>
> Q. And is that a system that you came up with to rate difficulties?
>
> A. Yes.

Bergmann (3/15/16) Dep. at 105. It is certainly appropriate for experts to prepare a summary of support for their opinions in this manner. If Plaintiffs believe there are deficiencies in the table, such as including data from similar types of slings or not including certain factors in the "Cost" column, these are matters upon which they may cross-examine her.

CONCLUSION

For the reasons set forth above, the Court should deny Plaintiffs' Motion to Exclude Certain Opinions of Cynthia Bergmann, M.D.

Respectfully submitted,

ETHICON, INC. AND
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CERTIFICATE OF SERVICE

I certify that on May 9, 2016, I electronically filed this document with the Clerk of the Court using the CM/ECF system which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

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